Integrated Diagnostic and Treatment Devices for Enroute Critical Care of Patients within Theater

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ABSTRACT

The combination of far-forward surgical hospitals, which vastly shorten time between injury and life-saving surgery, and employment of damage control surgery/resuscitation practices have been significant factors in the much improved survival rates observed during Operations Enduring and Iraqi Freedom as evidenced by the roughly 40% reduction in case fatality rate observed for OEF and OIF over the 2001-2005 period compared to that of the Viet Nam conflict. Post-operative patients coming out of these forward surgical hospitals are often moved within just a few hours following surgery and require high acuity care during transport. These patients are stabilized, but not necessarily stable, and are particularly vulnerable during Interfacility transport between theater hospitals, i.e., between Role 2 and Role 3 facilities or between Role 3 facilities. Interfacility transport of critical patients in theater normally takes place on US Army rotary-wing aircraft, but ground ambulances or even watercraft may be used if necessary. To help ensure positive patient outcomes during these transport missions the originating theater hospital provides an appropriately skilled critical care provider and medical equipment to support the patient during transport. The medical devices provided are the same portable patient monitor and therapeutic devices used in the originating hospital.

Use of multiple portable medical devices during Interfacility transport of critical patients is problematic, especially in the rotary-wing environment, which is characterized by high noise levels, extreme vibration, confined space, and low-to-no-light conditions all of which impede patient assessment and prompt intervention. This is troublesome as several adverse events can occur during transport including exsanguination, hypotension, hypoxemia, accidental extubation or loss of intravenous access, inadequate sedation / analgesia, hypothermia, and ventilator malfunction. Furthermore, portable medical devices must be attached to the litter or airframe prior to flight. The practice of distributing medical devices on and around the patient creates a considerable burden for both patient and providers. Use of multiple medical devices also poses significant logistical burdens due to the need to satisfy the various power and maintenance requirements of the individual pieces of equipment, including the need for multiple types of batteries. Therefore, use of an integrated critical care device providing both patient monitoring and therapeutic interventions would aid in overcoming these shortcomings.

For several years, the US Army, in collaboration with industry partners and the other services, has been involved in the development of integrated critical care devices that are small, rugged, lightweight, and able to attach to the litter without obstructing patient access. At present the United States Army Medical Materiel Agency is evaluating three such devices - the LS-1 developed by Integrated Medical Systems, Inc., the Lightweight Trauma Module developed by Impact Instrumentation, Inc., and the MOVES developed by Thornhill Research, Inc. These devices provide advanced critical care monitoring and ventilator capabilities. Each possesses the ability to accept, control and/or power other devices such as infusion pumps. The MOVES

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14. ABSTRACT

The combination of far-forward surgical hospitals, which vastly shorten time between injury and life-saving surgery, and employment of damage control surgery/resuscitation practices have been significant factors in the much improved survival rates observed during Operations Enduring and Iraqi Freedom as evidenced by the roughly 40% reduction in case fatality rate observed for OEF and OIF over the 2001-2005 period compared to that of the Viet Nam conflict. Post-operative patients coming out of these forward surgical hospitals are often moved within just a few hours following surgery and require high acuity care during transport. These patients are stabilized, but not necessarily stable, and are particularly vulnerable during Interfacility transport between theater hospitals, i.e., between Role 2 and Role 3 facilities or between Role 3 facilities. Interfacility transport of critical patients in theater normally takes place on US Army rotary-wing aircraft, but ground ambulances or even watercraft may be used if necessary. To help ensure positive patient outcomes during these transport missions the originating theater hospital provides an appropriately skilled critical care provider and medical equipment to support the patient during transport. The medical devices provided are the same portable patient monitor and therapeutic devices used in the originating hospital. Use of multiple portable medical devices during Interfacility transport of critical patients is problematic, especially in the rotary-wing environment, which is characterized by high noise levels, extreme vibration, confined space, and low-to-no-light conditions all of which impede patient assessment and prompt intervention. This is troublesome as several adverse events can occur during transport including exsanguination, hypotension, hypoxemia, accidental extubation or loss of intravenous access, inadequate sedation / analgesia, hypothermia, and ventilator malfunction. Furthermore, portable medical devices must be attached to the litter or airframe prior to flight. The practice of distributing medical devices on and around the patient creates a considerable burden for both patient and providers. Use of multiple medical devices also poses significant logistical burdens due to the need to satisfy the various power and maintenance requirements of the individual pieces of equipment, including the need for multiple types of batteries. Therefore, use of an integrated critical care device providing both patient monitoring and therapeutic interventions would aid in overcoming these shortcomings. For several years, the US Army, in collaboration with industry partners and the other services, has been involved in the development of integrated critical care devices that are small, rugged, lightweight, and able to attach to the litter without obstructing patient access. At present the United States Army Medical Materiel Agency is evaluating three such devices - the LS-1 developed by Integrated Medical Systems, Inc., the Lightweight Trauma Module developed by Impact Instrumentation, Inc., and the MOVES developed by Thornhill Research, Inc. These devices provide advanced critical care monitoring and ventilator capabilities. Each possesses the ability to accept, control and/or power other devices such as infusion pumps. The MOVES also includes an integrated 3 liter/minute oxygen concentrator. These devices possess central processing units that integrate medical functions and record patient physiological data and provider interventions. It is anticipated that future versions of these devices will be able to provide closed-loop control of oxygenation, ventilation, fluid resuscitation, sedation and analgesia; compute derived physiological parameters such as heart rate complexity; and provide telemedicine capability.

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1.0 INTRODUCTION

For several years, the U.S. Army, in collaboration with industry partners and the other services, has been involved in the development of integrated critical care devices -- small, rugged, lightweight devices to facilitate provision of high acuity care and improve patient safety during medical evacuation on air and ground ambulances. Miniaturization of medical device components has now made it possible to replace the several portable medical devices currently used to provide critical enroute care with a single integrated base device that provides patient monitoring and ventilation. This device also serves as an interface with accessory devices such as infusion pumps. At present, the United States Army Medical Materiel Agency, Fort Detrick, MD, is evaluating three such devices -- the LS-1 (formerly called the MEDEX 1000) developed by Integrated Medical Systems, Inc.; the Lightweight Trauma Module (LTM) developed by Impact Instrumentation, Inc.; and the MOVES, developed by Thornhill Research, Inc. These devices, which may be secured to the standard North Atlantic Treaty Organization (NATO) litter, provide advanced critical care monitoring and ventilator capabilities. Each possesses the ability to interface with and control and/or power accessory devices. The MOVES also features an integrated three liter/minute oxygen concentrator. These devices possess central processing units that integrate medical functions and automatically record patient physiological data and provider interventions. It is anticipated that future versions of these devices will be able to provide closed-loop control of oxygenation; ventilation; fluid resuscitation; sedation and analgesia; computer-derived physiological parameters, such as heart rate complexity; and telemedicine capability. The purpose of this article is to explain why the Army seeks to field integrated diagnostic and treatment device for enroute critical care, provide historical background on the Army's development efforts in this area, describe the Army's requirement for an integrated enroute critical care device, provide non-proprietary descriptions of three systems presently under consideration, describe the test program these candidate systems will be subjected to as part of the selection process, and discuss future applications of these technologies.

2.0 THE PROBLEM OF INTERFACILITY TRANSPORT BETWEEN THEATER HOSPITALS

Multiple factors, including the use of body armor, improved first responder care. Use of forward surgical hospitals and employment of damage control surgery/resuscitation practices have been instrumental in producing the much improved survival rates observed during Operations Enduring (OEF) and Iraqi Freedom (OIF). This was evidenced by the roughly 40% reduction in case fatality rate during 2001-2005, compared to that observed in previous major U.S. armed conflicts [6]. The relative contribution made by each of these factors to the improved survival rate has been difficult to determine; however, it is known that the use of forward surgical hospitals (e.g., Army Forward Surgical Teams and Combat Support Hospitals) reduces the time between wounding and life-saving surgery.

Trauma patients admitted to these forward surgical hospitals are subjected to damage control surgery followed by a period of intensive care then transported to either another theater hospital for definitive surgical care (i.e., interfacility transport), or to a Mobile Aeromedical Staging Facility for transport out of theater via U.S. Air Force fixed-wing aircraft [2,3,4]. Post-operative patients evacuated from these forward surgical hospitals

are often moved within just a few hours following surgery and require high acuity care (e.g., mechanical ventilation, multiple organ support) during transport. These patients are stabilized, but are not necessarily stable as they often experience hemodynamic and/or respiratory fluctuations during transport [3,7].

The majority of interfacility critical patient transports are via rotary-wing aircraft, which are utilized for their speed, although ground ambulances or watercraft may also be used if needed [3,4,9]. Lifts of opportunity are often used for these medical transport missions [3,4].

Post-operative patients are exposed to significant risk during aeromedical evacuation on rotary-wing aircraft. This is due to the harsh physical environment within the aircraft during flight and the limitations it places on medical attendants. The rotary-wing environment is characterized by extreme vibration, low-to-no-light conditions, confined space, and high noise levels. All of these hamper patient assessment and prompt intervention [3,4]. Lehmann, et al., 2009, observed clinical deterioration (hypotension, hypoxemia, and arrhythmias) in 30% of patients transported by helicopter between theater hospitals [9]. They also observed medical equipment failure in 17% of flights [9]. Several other adverse events can occur during rotary-wing transport including exsanguination, accidental extubation, loss of intravenous access, inadequate sedation / analgesia, and hypothermia [3,4].

To help ensure positive patient outcomes during medical evacuation missions, the originating theater hospital provides an appropriately skilled medical attendant, ideally a critical care nurse, physician assistant, or physician [2] to attend the patient during transport; although in many instances the medical attendant may in fact be a medic [4]. The originating theater hospital also provides medical equipment required to support the patient during transport [2,3]. The medical devices provided are the same portable patient monitor, ventilator, and other therapeutic devices used in the originating hospital [2]. The devices are known collectively as Patient Movement Items (PMI). The current Army PMI medical devices are the Protocol 206EL vital signs monitor (Welch Allyn Protocol, Inc., Beaverton, OR), the Impact Instrumentation 326 suction apparatus (Impact Instrumentation, Inc., West Caldwell, NJ), the Alaris MS III infusion pump (CareFusion, San Diego, CA), and the Impact Instrumentation 754 transport ventilator (Impact Instrumentation, Inc., West Caldwell, NJ).

Use of multiple PMI medical devices during interfacility transport of critical patients aboard rotary-wing aircraft poses challenges that can tax the ability of the medical attendant to effectively monitor and document the patient's condition and care, or to promptly intervene when needed. The limited cabin space greatly limits device placement options and it interferes with the attendant's ability to move about, which hampers the attendant's ability to see the various device displays and visual alarms. High noise levels make device audible alarms ineffective without the use of headphones. The high levels of vibration experienced during flight and the possibility of hard landings or crashes make it necessary to securely attach the PMI medical devices to either the litter or airframe in order to ensure crew safety. In some cases, when the number of clinically required medical devices exceeds the mounting capacity of the litter or airframe, some devices may have to be secured over the patient's body. The practice of distributing medical devices on and around the patient creates a considerable burden for both patient and medical attendant. It reduces device visibility and limits access to the patient and the devices. The weight of the medical devices is significant and can cause harm to the patient if placed on the patient's body.

When preparing for the patient transport mission, the medical attendant must also be cognizant of the differing electrical power requirements of the individual PMI devices and ensure that there is an adequate supply of the required batteries available for the duration of the flight. If use of vehicle power is permitted, the medical attendant must ensure that the necessary voltage converters are available. Also, the individual PMI devices have differing maintenance requirements (e.g., calibration cycles, test equipment, software maintenance, battery chargers, etc.) that can impact device availability.

The U.S. Army has sought to overcome these device-related challenges in enroute critical care by replacing the currently fielded PMI devices with an advanced, integrated critical care and treatment device that is smaller, lighter, and easier to use and maintain in austere environments. Selection and fielding of an integrated critical care and treatment device will make the medical attendant's work easier, facilitating provision of high acuity care and improving the patient's safety and probability for a positive outcome.

3.0 PREVIOUS ARMY ATTEMPTS TO IMPROVE ENROUTE CARE DEVICES

Early enroute care technology development efforts focused on consolidation of the PMI devices within a single platform. An early example of this was the development of the Life Support for Trauma and Transport (LSTAT), which began during the mid 1990s [8]. The LSTAT (Fig. 1 and 2) was developed by Integrated Medical Systems, Inc., Signal Hill, CA, under the technical direction of the Walter Reed Army Institute of Research, Silver Spring, MD, and the guidance of the Army Medical Materiel Development Activity, Fort Detrick, MD. The LSTAT was a self-contained critical care platform upon which the standard NATO litter was mounted. The PMI devices were integrated within the LSTAT's rugged shell; positioned under the litter so as not to limit access to the patient's body. Although the U.S. Food and Drug Administration would not at the time allow use of a single user interface, the device displays/user interfaces for the patient monitor, ventilator, infusion pump, and suction apparatus were all co-located within the LSTAT's head fairing assembly. The head fairing assembly also contained the patient breathing circuit and patient lead connectors. In addition to the standard PMI devices, the LSTAT also featured an integrated semi-automatic external defibrillator and blood chemistry analysis system.

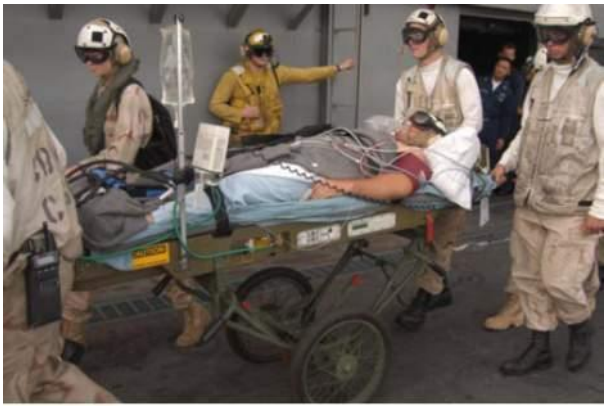

Figure 1: Patient Being Transported with the Life Support for Trauma and Transport (LSTAT).

The LSTAT possessed advanced capabilities including a central processing unit that captured and stored up to 72 hours of patient, intervention, and system data for later download, and an electrical power system capable of providing power to all of the LSTAT's medical subsystems. The LSTAT accepted a variety of external alternating and direct current power sources. It also possessed an integral, rechargeable battery capable of providing 30 minutes of autonomous power. The LSTAT possessed an on-board, non-standard oxygen cylinder that minimized space requirements, but proved to be difficult to replace or refill. The LSTAT was also designed to accept external oxygen sources.

Figure 2: View of LSTAT Headfairing Assembly.

The LSTAT was ruggedized to withstand the rigors of transport. It was heavily shielded to meet electromagnetic interference test requirements. The high degree of ruggedization and electromagnetic shielding along with the on-board battery made the LSTAT quite heavy, which adversely impacted its suitability for enroute care use. Its development did, however, prove the concept of an integrated critical care device.

During the early part of this decade, medical personnel at the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX, developed a simple but effective means to attach PMI devices to the NATO litter allowing safe, standardized device positioning. This device was the Special Medical Emergency Evacuation Device (SMEED). The U.S. Army Institute of Research subsequently licensed the SMEED technology to Impact Instrumentation, Inc, West Caldwell, NJ, who commercialized it [12]. The SMEED (Fig. 2) is a 20 pound stretcher bridge designed to secure the PMI devices to the standard NATO litter. It was developed to eliminate the need to stow PMI devices on the bodies of burn patients during transport. The PMI devices may be placed in a variety of positions on the SMEED, attaching with standard clips. The SMEED with attached PMI devices is normally affixed to the lower end of the litter where it spans over the patient's lower legs.

Figure 3: Special Medical Emergency Evacuation Device (SMEED) Attached to Litter and Outfitted with Patient Monitor, Ventilator, Suction Apparatus, and Oxygen Cylinder.

The SMEED has been extensively used by U.S. Air Force Critical Care Aeromedical Transport Teams [7](Fig. 3 and 4), U.S. Army Burn Flight Teams [11], and U.S. Marine Corps medical evacuation teams;

however, U.S. Army deployed medical units have largely refrained from using the SMEED during interfacility transport of critical patients due to the SMEED's incompatibility with the external fixation devices used to stabilize extremity bone fractures during medical evacuation. The SMEED must be positioned over the patient's upper body whenever external fixation devices are used on the patient's legs. This, of course, limits accessibility to the patient's upper body impeding patient assessment and intervention (e.g., chest compressions). While the SMEED has proven to be an effective means to standardize placement of PMI devices on the litter and eliminate the need to stow them on the patient's body, there is no integration of device function nor is there improvement in logistic supportability; so issues pertaining to multiple displays/user interfaces, need for multiple types of batteries, etc., remain.

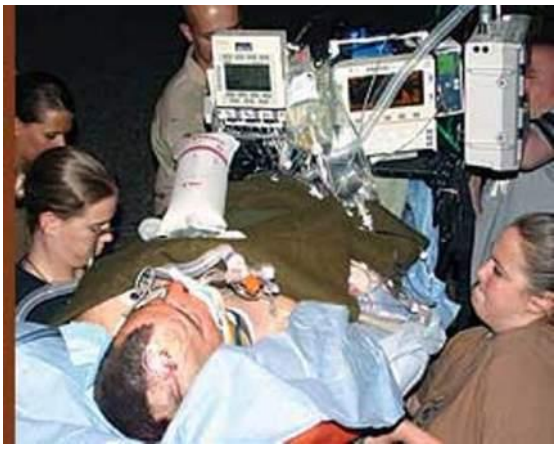

Figure 4: Patient Being Transported with SMEED and Attached Medical Devices.

4.0 ARMY REQUIREMENT

The Army Medical Department Center and School, Directorate for Combat and Doctrine Development, Fort Sam Houston, TX, prepared a capability development document describing its requirement for a lightweight integrated critical care monitoring and treatment device [1]. This requirement is summarized below.

The device will be a portable, single patient, critical care, and evacuation support device combining advanced physiological monitoring, pulmonary ventilation, oxygenation, and data storage capabilities. Its data storage capability will allow it to capture clinical parameters and waveforms. It is an objective requirement that this device will integrate with a self-contained continuous oxygen generating system to reduce the logistical footprint and operational risk of transporting oxygen cylinders.

This device will be employed at medical treatment facilities (MTFs) for patients who have been stabilized but remain hemodynamically unstable and require close, continued life support to survive the evacuation distance to the next higher level of care. The device will secure to the NATO litter or to a portable attaching device which then secures to the NATO litter.

The device will serve as a critical care support platform for those patients being transported from Role 2 (e.g., Forward Surgical Team) or 3 (i.e., Combat Support Hospital) MTFs supporting a brigade or other organization. Patients requiring immediate surgical intervention and/or other stabilization prior to evacuation may be transferred to the supporting forward surgical team or combat support hospital where life-saving

procedures will be performed. Once the patient is stabilized for transport from the Forward Surgical Team, the patient will be placed on the device for evacuation to the Combat Support Hospital, or other higher-level MTF. Transport may be accomplished by ground vehicle or by aeromedical evacuation aircraft, both rotary and fixed wing. Throughout the evacuation process, the device will continue advanced critical care monitoring and medical life-support essential for post-stabilized patients who remain at risk of sudden life-threatening changes to their clinical status. Patients arriving at the Combat Support Hospital can either be removed from the device for additional care, or continue to be supported by the device while awaiting further evacuation.
The device must be cleared by the U.S. Food and Drug Administration. This is an absolute requirement as the U.S. Army will not field any medical devices that have not been first approved for marketing by the U.S. Food and Drug Administration.

The device must be suitable for providing critical care in austere environments. Ideally, the system will weigh 15 to 30 pounds. It must meet current U.S. military test requirements for use on rotary- and fixed-wing aircraft. It must be able to securely attach to the NATO litter either directly or via a detachable mounting device. It must also be able to endure storage and use under extreme temperatures, and be able to be transported and used in ground vehicles without damage.

The device will capture, store, and display both patient and system information for a minimum of 12 hours. The device will have an open architecture permitting export of patient clinical parameters and waveforms.
The device must accept and operate from 110/220 volts alternating current, 50/60 Hz, or 8-30 volts direct current. The device will have a rechargeable battery capable of operating for 4 hours if external power is lost. The integral battery shall recharge when external power is applied. The battery shall be "hot-swappable," i.e., capable of being exchanged during operation of the device without interruption of power.

The device will accept oxygen *United States Pharmacopeia* (USP), high and low pressure from external sources. Ideally, the device will generate oxygen USP at the rate of 3-5 liters per minute to support mechanical ventilation. The device will provide oxygen therapy through invasive and non-invasive delivery modes for patients. The device will possess a filtration system to protect ventilated patients from aerosol chemical, biological, radiological, and nuclear contaminants.

A detachable, or hand held monitor display that can display data for multiple patients is required. The device will electronically capture, measure, and display patient physiological parameters. The device will have three separate channels for invasive pressure catheters. The device will have clinical parameters and waveforms that are easily seen during movement of the evacuation platform. The device will have audible and visual alarms that are effective and accurate while operating in the evacuation platform. The device will capture, store, and display both patient and system information from attached clinical components (e.g., infusion pumps, oxygen concentrator, suction apparatus).

5.0 DESCRIPTION OF CANDIDATE SYSTEMS

Market investigation conducted by the U.S. Army Medical Materiel Agency as well as by the U.S. Air Force identified three new systems that may satisfy the Army's requirement. They are the LS-1 (formerly called the MEDEX 1000) developed by Integrated Medical Systems, Inc., Signal Hill, CA (Fig. 5), the Lightweight Trauma Module (LTM) developed by Impact Instrumentation, Inc., West Caldwell, NJ (Fig. 6), and the MOVES developed by Thornhill Research, Inc., Toronto, Ontario (Fig. 7). These are all military-unique devices that were developed with significant U.S. military financial support.

Figure 5: The LS-1 Manufactured by Integrated Medical Systems, Inc., Signal Hill, CA.

These devices, which are all indicated for both adult and pediatric patients, are lightweight systems designed to attach either directly to a NATO litter or attach to a SMEED. They are capable of providing advanced critical care monitoring including electrocardiogram, invasive and non-invasive pressures, body temperature, pulse oximetry, end tidal carbon dioxide, and respiratory mechanics. These devices utilize single graphical user interfaces (GUI) from which all device functions may be controlled and upon which all patient numerical and waveform physiological data are displayed. These devices are also designed so that the GUI may be easily seen from multiple positions. All three alternatives possess central processing units that integrate medical functions and record patient physiological data, clinical interventions, and system data for later down load. Furthermore, all three candidates possess electrical power systems capable of accepting a variety of external alternating and direct current power sources. Each also includes rechargeable, replaceable batteries to provide power for autonomous operation.

Figure 6: The Lightweight Trauma Module (LTM) Manufactured by Impact Instrumentation, Inc., West Caldwell, NJ.

Each of the three candidate devices possesses integrated mechanical ventilators capable of multiple modes of operation and able to accept low and high pressure oxygen sources. The MOVES also possesses an integrated oxygen concentrator that produces three liters of oxygen per minute.

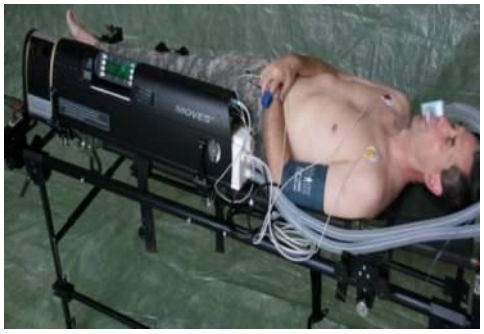

Figure 7: The MOVES Manufactured by Thornhill Research, Inc., Toronto, Ontario.

All three devices possess the ability to accept, control and/or power other accessory devices such as infusion pumps, suction apparatuses, and oxygen concentrators.

6.0 TESTING OF CANDIDATE SYSTEMS

The United States Army Medical Materiel Agency, Fort Detrick, MD, is evaluating the LS-1, the LTM, and MOVES as part of its acquisition process to select and procure the best value system for fielding in 2011. This evaluation will include technical and operational testing, portions of which will be conducted in coordination with the U.S. Air Force. The test program will begin in February 2010 and is scheduled to conclude in August 2010. The testing will be conducted in segments beginning with an initial clinical user assessment, which will be followed by airworthiness certification evaluation and transportation and storage environmental testing. The test program will conclude with operational and Reliability, Availability, and Maintainability (RAM) testing.

An initial clinical user assessment will be conducted at the U.S. Air Force Center for the Sustainment of Trauma & Readiness Skills located at the University of Cincinnati. During this assessment, Army and Air Force clinicians will use the three alternative systems to treat simulated critical care patients in a fixed-facility setting. The purpose of this assessment is to ensure the devices are suitable for use by military clinicians in the treatment of trauma casualties.

Airworthiness Certification Evaluation of the three candidate systems will be carried out at the U.S. Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL, in accordance with joint airworthiness requirements. This testing is required to ensure that operation of the devices will not adversely impact the aircraft or welfare of the aircrew and it ensures that the devices operate as intended in the aviation environment. This testing will encompass human factors testing; electromagnetic interference emission and susceptibility testing; electrical safety; vibration testing (rotary-wing, fixed-wing, and ground vehicle); device operation under hot, cold, and humid conditions; testing for intrusion by sand, dust, and rain; altitude and rapid decompression testing; and explosive atmosphere testing.

USAARL will also conduct transportation and storage testing of the three devices under consideration. This testing will focus on transportation and storage of the device when it is contained in its protective shipping container. This testing will ensure that the candidate devices are able to withstand transport in the back of trucks, etc., and that they will not be adversely affected by long-term storage in extreme environments.

Operational testing of the three candidate devices will be conducted by the Army Medical Department Test Board using Army medical personnel. This testing will be conducted to evaluate the operational effectiveness and suitability of the candidate devices with respect to the deployed health care mission.

The U.S. Air Force Medical Evaluation Support Activity located at Fort Detrick, MD will subject the three candidate devices to RAM testing. This purpose of this testing will be to assess system readiness, system quality, operational costs, and logistic supportability.

7.0 FUTURE DEVELOPMENT OBJECTIVES

The three integrated critical care devices currently under consideration all possess central processing units that provide integrated control and display of all clinical functions as well as record patient physiological data and provider interventions. These capabilities alone will offer significant improvement over currently fielded critical care monitoring and treatment devices. They will enhance the ability of a skilled critical care practitioner to provide high acuity care in the austere transport environment, but what about the medical attendants who are not so well trained, skilled, or experienced in critical care? Further enhancements are expected to come to the fore as technology continues to improve and the U.S. Food and Drug Administration becomes more familiar with these new technologies.

Clinical decision support algorithms that alert the medical attendant to changes in the patient's condition and provide instructions to guide the medical attendant's clinical interventions will likely be the first of these advanced capabilities to come to fruition as they offer the least regulatory risk. Clinical decision support algorithms will allow medical personnel with varied skills, training, and experience to provide uniformly high quality care to critical patients during interfacility transport. With improved computing capability also comes the potential for improved medical communications, telemedicine capability, and remote operation -- features that could provide useful links between Role 3 critical care experts and medical attendants caring for patients in air or ground ambulances. Embedded tools to provide sustainment training to users will also be of benefit.

The increasing computing capability provided by integrated critical care devices is expected to eventually lead to adoption of entirely closed-loop, autonomous patient care systems. These systems are designed to continuously and automatically monitor the patient's physiological status. Changes in the patient's condition prompt an immediate and appropriate therapeutic response without human intervention. Closed-loop controller algorithms are being developed to manage administration of oxygen, resuscitative fluids, sedatives, and analgesics [10]. Closed-loop critical care systems will be especially advantageous in the dark, noisy environments common to medical evacuation [7,10]. Use of fully autonomous, closed-loop critical care devices for enroute care offers several potential benefits, including faster intervention; consistent, physiology-based treatment; appropriate ventilator operation and management independent of the medical attendant's skill level; and conservation of limited consumable resources such as resuscitative fluids, oxygen, and electrical power [10].

The Army Institute of Surgical Research, Fort Sam Houston, TX is currently working to develop algorithms that rapidly recognize the series of events leading to physiological decompensation and alert the medical attendant, so that life saving interventions can be made before decompensation occurs [5]. Future integrated critical care devices will be logical hosts for these algorithms, which require high fidelity physiological sensors and substantial computing power. These predictive algorithms will also make closed-loop life support systems more robust [5].

The computing capability offered by this new family of medical devices is expected to provide supportability benefits as well. Medical device calibration and software maintenance is costly, time consuming, and can

adversely affect device availability. Remote calibration and installation of scheduled software upgrades via the internet will reduce the logistic footprint of fielded medical devices, increase device availability, and reduce maintenance costs. Embedded maintenance diagnostics and maintenance training will benefit maintainers in theater, and will also reduce maintenance costs. Advanced integrated critical care devices such as the LTM, LS-1, and MOVES are expected to be among the first to implement these capabilities.

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